UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)))))	MDL NO. 1456 CIVIL ACTION: 01-CV-12257-PBS Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO	))	Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., No. 06-CV-11337-PBS	))))	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES INC.'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO DISALLOW DEFENDANT'S NEW EXPERT OPINIONS

INTRODUCTION

Plaintiffs' motion to disallow what it incorrectly characterizes as "new expert opinions" from Abbott's expert is an exaggerated, disingenuous attempt to subvert easily understood, non-controversial information that will assist the Court in evaluating the reliability of Dr. Duggan's extrapolated "difference" computations. The materials that Plaintiffs seek to exclude, which will be included in a binder presented to the Court, are precisely the type of information the Court has expressed a desire for as it assesses the admissibility of Duggan's extrapolations. The opinions and information at issue are neither new nor complex.

In particular, Plaintiffs seek to exclude a showing of the variability – expressed in a well-established statistical measure known as standard deviation – of ***Duggan's own "fraud ratio" calculations*** across the 19 States and handful of Part B Medicare Carriers that Duggan analyzed. The standard deviation figures respond to Duggan's new analysis and hearing testimony, address Plaintiffs' criticisms of Abbott's experts (just as Duggan's new analysis, delivered shortly before hearing, responded to Abbott's criticisms of his work), and support opinions ***already fully expressed*** by Abbott's experts about the need for valid, representative samples. The point is

simple, undisputable, and certainly not news to Plaintiffs or their experts: substantial variability in the impact of Duggan's "but-for" prices across the States and Carriers where Duggan had necessary data decreases the statistical precision and reliability of applying conclusions to States and Carriers where he lacks the necessary data. Abbott's experts have stated this fundamental point from the beginning. There are no "completely new theories," and no "new, complex analyses." (Plfs. Mot. at 1, 3.)

Ironically, Plaintiffs' motion runs counter to its own approach to the *Daubert* hearing. Any "new analyses" conducted by one of Abbott's experts is dwarfed by the extensive, complicated new work that Plaintiffs sprung on Abbott shortly before the *Daubert* hearing. Duggan performed this new work well after multiple reports and depositions and after Abbott's *Daubert* challenge was fully briefed by both parties, purportedly to "take another look at these issues." (Ex. A.) Apparently, Plaintiffs think that, while they can make extensive use of Duggan's new "look at the issues," Abbott and its experts should have no opportunity to respond to Duggan's new analysis or the criticisms leveled against Abbott's experts in the briefing. Plaintiffs' own conduct should estop their instant motion.

Finally, the standard deviation figures are neither "complex" nor "misleading." (Plfs. Mot. at 3.) Rather, they are simply Excel-driven computations that – as Plaintiffs must admit – are "rooted" *in Duggan's own figures* (including new Duggan "difference" figures delivered shortly before the hearing). (*Id.* at 2.)[1] Unless Plaintiffs lack confidence in Duggan's own "fraud ratios" or the capability of Microsoft Excel to perform the basic standard deviation formula embedded in that software, there are – quite unlike Duggan's new analysis – no new

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[1] Abbott's experts did not even have Duggan's "fraud ratios" for nine of the 19 States that Duggan eventually evaluated until he served his new analysis shortly before the Daubert hearing. Moreover, the source files that Duggan included with that new analysis did not themselves contain his fraud ratios. After gaining familiarity with and verifying Duggan's source code, Abbott's experts had to compute those figures themselves (using Duggan's "differences" for those States).

numbers to verify or correlate. Abbott has fully disclosed all material related to the standard

deviation figures consistent with the Court's instructions. Abbott even provided Plaintiffs with

slides fully explaining the relevance of the standard deviation figures. (*See* Plfs. Mot., Ex. 4 at

12-13.) There are no surprises here. Plaintiffs' motion should be denied.

ARGUMENT

I. THE STANDARD DEVIATION FIGURES DO NOT PRESENT ANY "NEW OPINIONS" OR ANY "COMPLETELY NEW THEORIES."

From his expert report through his deposition, Abbott expert Jim Hughes (who will be

prepared to discuss the standard deviation figures) has repeatedly opined that the *variability* in

how Carriers and States determined payments for the Subject NDCs and J-Codes, coupled with

Duggan's inability to use a representative sample of claims from all Carriers and States (an

inability caused by DOJ's spoliation of relevant evidence), renders Duggan's extrapolations

statistically invalid and unreliable. For instance, Dr. Hughes' report stated (emphasis added):

- "For Medicare, [Duggan's] estimates are based on a small amount of *variable data* that is in no manner a random or representative sample of the data. From these flawed data, he performs extrapolations across time and space that have no statistical validity." (Ex. B at 2.)

- "The available arrays show this assumption to be baseless, *as carriers' arrays vary greatly* at a single point in time. He speculates, but neither knows nor demonstrates that the array for a given carrier in a given period is the same for that carrier for all other periods where he does not have an array. Again, Dr. Duggan's own evidence shows this assumption to be without basis, as *individual carriers' arrays vary across time*. Any extrapolation from such a slipshod sample to other carriers or periods of time is baseless and without merit." (*Id.* at 19.)

- "By extrapolating in this way, [Duggan] makes the *baseless and untested assumption that the reimbursement systems and resulting reimbursements are the same between his exemplar states and the other 38*. He provides no factual basis for such an assumption." (*Id.* at 42.)

- "It is not conservative to base one's extrapolations on an unscientific, nonrandom and unrepresentative sample of the states, *assuming away differences between his exemplar states and the other 38 states*." (*Id.* at 45.)

Dr. Hughes reiterated that opinion during his deposition. For example (emphasis added):

- "What I'm saying is we know [the Medicare arrays] *they're not all the same*. We don't know why they're not all the same. They're very ad hoc. They're supposed to be revised every quarter. They're not revised every quarter. *There's all sorts of reasons that these things vary across time and across carriers*." (Ex. C at 245).

- "[Duggan] has every reason to believe from the evidence that he does have that the arrays that he doesn't have *are dissimilar, are not the same*. And yet he just plows right ahead, says I'm going to extrapolate based on the average of the arrays that I do have, and I'm just going to assume that these things are basically the same. That leaves us in the situation that his extrapolations could be *highly accurate*. It leaves us with the situation that *his extrapolations could be wildly inaccurate*. And the reason for that is he has provided us with no reason to believe that the assumption that he is making has any validity whatsoever." (*Id.* at 248.)

In their briefing, Plaintiffs have repeatedly criticized Abbott for allegedly "cherry-picking" instances where Duggan's calculations are susceptible to error. Moreover, during the hearing, Duggan supported his extrapolations by repeatedly stressing the alleged similarity of the payment methodologies across the States and Carriers. (*See* Ex. D at 60 ("the similarity [across the States] with respect to pharmaceutical reimbursement during this time period is very high"), *Id.* at 76 (stating there is a "huge amount of similarity" across the Carriers in the arrays). Abbott believes those assertions, as pertinent to this motion, are not factually accurate.

Rather than be accused of "cherry picking," Dr. Hughes had Excel compute some basic figures using Duggan's own data across all of the States, Carriers, and time periods where he had the necessary data to perform a "difference" calculation. These figures rebut Duggan's statements about the "similarity" of the States and Carriers, and serve to demonstrate the variability across the Carriers and States in a fair, comprehensive, and readily understandable way. The process for computing these figures was not "complex." Dr. Hughes transported Duggan's so-called quarterly "fraud ratios" for the Subject NDCs and J-Codes into Excel spreadsheets (*see, e.g.*, Plfs. Mot., Ex. 3), and asked Excel to simply identify the mean "fraud ratio," the minimum "fraud ratio," the maximum "fraud ratio," and then compute the standard deviation of the "fraud ratios" for each quarter-NDC/J-Code combination. The mean, minimum,

and maximum figures took no computation at all; they are just Duggan's difference figures placed into charts.[2] Dr. Hughes then asked Excel to compute the range of plus and minus 1 and 2 standard deviations from the mean, as well as a common statistic known as "relative standard deviation" (simply the standard deviation divided by the mean).

After Excel computed the figures, Dr. Hughes prepared graphs to illustrate the figures in a non-biased, non-"cherry-picking" way to assist the Court in making meaningful sense of the figures. The graphs illustrate the variability of Dr. Duggan's "fraud ratios" across the Carriers and States – variability that comes from Duggan's computations, but that Duggan chose to ignore.[3] For example, one graph shows the "Standard Deviation of Difference Fractions Across the 19 States Dr. Duggan Analyzed 1999 Q4 (Highest Expenditure Period)." (*See* Plfs. Mot., Ex. 4 at 2.) It shows, for instance, that Duggan's "fraud ratio" for the highest expenditure NDC (00074653301) and quarter (Q4 1999) exhibits variance ranges of approximately 40% (one standard deviation) and 60% (two standard deviations). Similarly, other graphs show there is no consistent pattern either across or within the Part B Carriers in the impact of Duggan's revised prices. (*See id.* at 8, 11.)

Had there been any doubt as to the "reasoning" behind the standard deviations figures (and there was not), Abbott delivered to Plaintiffs a bullet-point slide making that make perfectly clear. For example, the slide states:

- "The difference fractions Dr. Duggan computes from his "samples" of States and Carriers serve as the foundation of his extrapolations to other States and Carriers.

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[2] There is *no basis whatsoever* for Plaintiffs to object to any demonstratives, such as the first graph in Plaintiffs' Exhibit 4, that merely plot Duggan's mean, minimum, and maximum "fraud ratios." Plotting someone else's figures into a chart is not a "new analysis."

[3] Indeed, instead of expressing confidence in the reliability of his extrapolations in an unscientific, narrative, "trust me" fashion, Duggan should have computed these figures himself to assess the reliability of his findings. (*See* Ex. C at 96 ("[I]t is my judgment . . . the estimates I've come up with are incredibly reliable, are very, very reliable.") So far as Abbott can tell, he failed to do so.

Substantial variation in Dr. Duggan's difference fractions reduces the precision and reliability of his findings."

- "Substantial variation in Dr. Duggan's difference fractions emphasizes the importance of using valid samples which are random and representative of all claims being analyzed."

In sum, there are no "new opinions," nor any "completely new theories." Indeed, it is difficult to conceive a situation where an adversary has been given more advance notice of precisely what his opponent was going to present during a *Daubert* hearing.

II. THE STANDARD DEVIATION FIGURES ARE NEITHER "COMPLEX" NOR "MISLEADING."

Plaintiffs greatly exaggerate the complexity and breadth of the standard deviation figures, suggesting that this information is "complex" and contains "29 separate worksheets" with "thousands of calculations" and a "giant 1,758 row conglomeration. (Plfs. Mot. at 3-4.) The only thing misleading here is Plaintiffs' description of what was done.

In fact, the standard deviation figures are not complex at all. As discussed above, Dr. Hughes simply transported Duggan's "fraud ratios" into Excel and asked the software to compute standard deviation figures of Duggan's ratios for every NDC/J-Code-quarter where Duggan used state claims data (Medicaid) or arrays (Medicare) to compute a difference in spending. It is *one basic set of calculations* across *Duggan's* NDC/J-Code-quarter combinations. Plaintiffs' suggestion that Abbott has somehow dumped "20,000" new figures that it must verify is false. Abbott even provided Plaintiffs with electronic versions of the spreadsheets so they could see the formulas and run the calculations themselves.

Nor are these figures in any way "misleading," "cherry-picked," or presented in any "skewed" fashion. (*Id.* at 3-5.) Plaintiffs provide no explanation to support these allegations. Standard deviation has been a well-established, often-used statistical measure of variability for decades. It is a straight-forward calculation, and it was not "skewed."

And there has been no "cherry-picking." For Medicaid, Dr. Hughes choose to graph the variability across the 19 State "fraud ratios" for the fourth quarter of 1999 simply because it was the highest expenditure quarter in the claims period. As the Court can see from the supporting materials (Exhibit 3 of Plaintiffs' motion), there is nothing unusual about the variability exhibited in that quarter. For Medicare, Dr. Hughes chose to focus some the graphs on the J-Code 7050 because it comprises a vast majority of Duggan's extrapolated Medicare "difference" for Part B Carriers. The supporting materials and other graphs demonstrate extensive variation in Duggan's "fraud ratios" across all 5 of the J-Codes Duggan analyzed.

III. THE STANDARD DEVIATION FIGURES WERE FULLY DISCLOSED CONSISTENT WITH THE COURT'S INSTRUCTIONS.

Abbott has fully disclosed all aspects of the standard deviation figures consistent with the Court's instructions. Plaintiffs have had the figures for a week-and-a-half, the same length of time that Abbott had to decipher Duggan's new, and considerably more complicated, analysis. Plaintiffs misquote what the Court said during the *Daubert* hearing. The Court did not say that Abbott could not use new charts; Abbott has not yet even presented its witnesses. Indeed, the Court made it perfectly clear that Abbott was entitled to respond to Duggan's new work. (Ex. D at 35.) The Court merely instructed the parties to provide any "new charts" or "new data" ***in advance of the next hearing*** so that opposing counsel would have an opportunity to correlate the data. (Ex. E at 84.) Abbott has done exactly that.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion should be denied.

Dated: January 20, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 20th day of January, 2010.

/s/ David S. Torborg
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